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HL

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/961,083	10/30/97	CHOI G	PB340P2

022195
HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE MD 20850

HM12/0622

EXAMINER	
HINES, J	
ART UNIT	**PAPER NUMBER**
1641	13

DATE MAILED: 06/22/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.	Applicant(s)
08/961,083	Choi, et al
Examiner	**Group Art Unit**
Ja-Na Hines	1641

☒ Responsive to communication(s) filed on *Apr 30, 1999*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *10, 11, 14, 17, 18, 21, and 198-262* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) *198-235, 237-260, and 262* is/are allowed.

☒ Claim(s) *11, 14, 17, 18, 21, 236, and 261* is/are rejected.

☒ Claim(s) *10 and 21* is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *13*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Applicant's election with traverse of Super Group I in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the examination of all the groups does not entail a serious burden. This is not found persuasive because there would be a severe burden on the Office to search all of the sequences and permutations in Super Group I due to the numerous amount of sequences presented.

The requirement is still deemed proper and is therefore made FINAL.

Amendment Entry

2. The amendments filed January 13, 1999 and April 30, 1999 have been entered. Claims 1-9, 12-13, 15-16, 19-20 and 22-197 are canceled. Claims 10-11, 14, 17-18, 21 and 198-262 are pending in this Office Action.

Priority

3. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

Specification

4. The disclosure is objected to because of the following informalities: The new address of ATCC is 10801 University Boulevard, Manassas, VA 20110-2209. Appropriate correction is required.

5. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

6. Claims 10 and 21 are objected to because of the following informalities: Both claims are dependent upon canceled claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made

herein. In order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance showing that:

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c)the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

This requirement is necessary when a deposit is made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each member State.

8. Claim 17 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of attenuating a *Streptococcus* infection, does not reasonably provide enablement for a method of preventing a *Streptococcus* infection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The specification fails to teach how to formulate and use the claimed vaccines. The term "vaccine" encompasses the ability of the specific antigen to induce protective immunity to a *Streptococcus* infection or

disease induction. The specification claims that the vaccine plays a role in the prevention and attenuation of the *Streptococcus* genus infections.

The specification does not provide substantive evidence that the claimed vaccines are capable of inducing protective immunity which would prevent *Streptococcus* infections. This demonstration is required for the skilled artisan to be able to use the claimed vaccines for their intended purpose of preventing *Streptococcus* infections. In view of the absence of working examples for a method of vaccinating against *Streptococcus* infections which prevents infections, the breadth of the claim, and the unpredictable state of the art with respect to vaccinating against *Streptococcus* infections, it would require undue experimentation for one skilled in the art to practice the entire scope of the claimed invention. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed vaccines, i.e. would not be able to accurately predict if protective immunity has been induced.

The ability to reasonably predict the capacity of a single bacterial immunogen to induce protective immunity from in vitro antibody reactivity studies is problematic. Ellis exemplifies this problem in the recitation that "the key to the problem (of vaccine development) is the identification of the protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies" (page 572, second full paragraph). Unfortunately, the art is replete with instances where even well characterized antigens that induce an in vitro neutralizing antibody response fail to elicit in vivo protective immunity. See Boslego et al. wherein a single gonococcal pillin protein fails to elicit protective immunity even though a high level of serum

antibody response is induced (page 212, bottom of column 2). Accordingly, the art indicates that it would require undue experimentation to formulate and use a successful vaccine the prevents *Streptococcus* infections without the prior demonstration of vaccine efficacy.

The specification fails to teach the identity of other isolated polypeptides with the claimed characteristics, i.e. capable of inducing protective immunity or preventing infection of any member of the *Streptococcus* genus. Further, the specification fails to provide an adequate written description of other polypeptides with this ability, the skilled artisan would be required to de novo locate, identify and characterize the claimed polypeptide. This would require undue experimentation given the fact that the specification is completely lacking in teachings as to other polypeptides with the claimed characteristics.

9. Claims 18, 21, 236 and 261 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are incomplete. There is no correlation step that relates the detected hybridization (claim 18 or 236) or the detected of the antibody-antigen complex (claim 21 or 261) to the *Streptococcus* nucleic acids or the antibodies in a biological sample.

10. Claims 11, 14 and 17-18 are indefinite. Claims 11 and 18 are vague in the recitation of "any of the polypeptides described in Table 1" (claim 11) and "one or more of the above-

described nucleic acid probes" (claim 18). The claims do not recite the election of nucleic acid sequences encoding the polypeptide of SEQ ID NO 55 and/or 56. Please amend the claims to reflect the appropriate elections.

Allowable Subject Matter

11. Claims 198-235, 237-260 and 262 are allowable because the prior art does not teach or fairly suggest using the method an isolated nucleic acid molecule comprising the polypeptide encoded by SEQ ID NO: 55 or 56 or any of the methods associated with the polypeptide.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines

June 14, 1999

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641